REMARKS/ARGUMENTS

In the most recent Office Action, claims 1, 2, 4, 10 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys (U. S. Patent No. 4,657,024). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys and Hopkins. Claims 5, 6, 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10 and 13, and further in view of Hopkins. With this response, Applicants have canceled claims 10-12. Claims 3, 7-9, 15 and 16 have previously been canceled.

The present application is directed to an introducer sheath. The introducer sheath includes a proximal shaft portion and a distal tip section, each formed of FEP. The distal tip section comprises high loadings of a radiopaque material.

It is known to provide introducer sheaths with discrete proximal and distal portions. Generally, a proximal portion comprises an elongated, relatively inflexible shaft that provides strength during insertion of the sheath into the vasculature. A distal portion comprising a short, relatively flexible tip is bonded to the proximal shaft portion, in order to minimize vessel wall trauma that may arise from the use of harder tips. Frequently, the distal tip portion is made more radiopaque that the proximal shaft. This enables the clinician to more clearly identify the distal tip under fluoroscopy. Tips are generally made radiopaque in one of two ways. One way involves placing a metal radiopaque marker band circumferentially around the distal tip, which band is spaced a defined distance from the tip. The other way involves forming the distal tip section from a polymer that is amenable to high loadings of radiopaque material.

When joining such proximal and distal sections, it is important to ensure that a reliable bond is established between them. The bonding zone between the distal tip and the proximal shaft realizes very high stresses, because this zone is at or very near the area that gets the most bending forces as the sheath is passed through the vasculature. Relatively large differences in material properties across a short bond zone further concentrate the stresses in the bond zone, making the bond susceptible to failure. The separation of a short tip segment from the remainder of the sheath results in a potentially dangerous embolus free floating in the vasculature. The embolus would eventually lodge somewhere, and form an occlusion to hinder blood flow to tissue. In order to assist in the formation of a more reliable bond, some

sheaths utilize the same, or a very similar, polymer in both the shaft and the distal tip portions. An example of such a polymer that is commonly used as both the shaft and distal tip is a polyether block amide, such as nylon.

When it is desired to make the distal tip section of such a sheath more radiopaque than the proximal section, the form of the radiopaque material to be utilized must be considered. Although a radiopaque band positioned circumferentially on the distal tip section is readily visible under fluoroscopy, such bands impart rigidity to the sheath at a very portion in which flexibility is an important consideration. In addition, even though the ring is visible under fluoroscopy, it is generally positioned a defined distance, such as ¼ inch, from the distal end of the sheath. This requires the clinician to estimate the distance from the ring to the end of the sheath. This distance can be critical when the physician is attempting to determine when to deploy an interventional device, such as a stent, from the end of the sheath. The use of a highly loaded radiopaque distal tip section alleviates these concerns. However, such distal tip sections must be formed of a material that is capable of forming a reliable bond with the proximal shaft portion, and that is capable of providing sufficient radiopacity for visualization under fluoroscopy.

As stated, both the main body shaft portion and the distal tip portion of the inventive introducer sheath are formed of FEP. Forming both sheath portions from the same polymer, in this case FEP, insures a good molecular mix of molten materials, and the formation of a particularly reliable bond. The distal tip portion includes high loadings of radiopaque particles, resulting in a distal tip portion that is distinctly more radiopaque than the main shaft portion. FEP is a favored polymer for use in introducer sheaths due to its low coefficient of friction. Having a low coefficient of friction allows the physician to pass stents, catheters and other interventional devices through the sheath with only a minimum of resistance. In addition, FEP is known to have good flexibility and kink resistance in fairly thin walls, which are important qualities in an introducer sheath that is to be used in accessing remote vascular sites.

Although highly loaded radiopaque catheter tips have been known, highly loaded FEP materials that are capable of functioning as distal tips have not. The high percent radiopaque material can result in a material that is as highly radiopaque as the stiff metal bands presently used with FEP. As a result, the use of the band can be eliminated, resulting in a tip that is

more flexible throughout its length than a sheath having a metal marker band, and that enables the clinician to distinctly view the location of the distal end of the sheath.

The distal tip of the catheter described in the primary Parker reference was made of a polyether block amide material, with nylon being a named example. The tip includes high loadings of tungsten to impart radiopacity. The shaft member of the Parker reference comprises an inner layer of PTFE, a wire braid overlaying the PTFE, and an outer layer of polyether block amide. The outer layer of polyether block amide extends distally a greater distance than the inner layer and the braid, such that the tip member is thermally bonded to the polyether block amide portion of the main shaft. The Parker reference does not teach the use of FEP as a material for either the distal tip or the main shaft body.

The secondary Coneys reference was cited for teaching the use of radiopaque-loaded FEP as a polymeric material in a medical tube. Applicants don't dispute that radiopaque-loaded FEP has been used, in some form, in medical tubes. However, the use of a radiopaque-loaded FEP layer fully embedded in virgin FEP, as described in Coneys is a far cry from its use in the present invention. The fully embedded, radiopaque layer comprises high amounts of FEP. However, when the radiopaque layer is embedded in the tube as described in the patent, the radiopacity of the tube is greatly reduced, such that the radiopaque material only comprises between 12-25% of the total weight of the material making up the tube. Col. 3, lines 63-65. Coneys completely embeds the radiopaque layer to avoid certain perceived problems that would arise if such material was not embedded. These problems include the possible chemical reactivity of exposed radiopaque material with body tissues, and a relatively high coefficient of friction that may result from the high loadings of radiopaque particles. Col. 1, line 50 to Col. 2, line 12.

Sandwiching pure FEP layers around a highly loaded radiopaque layer in Coneys results in a structure that is much more complicated, and costly, than the arrangement in the claimed invention. In addition, in the inventive sheath, such actions are unnecessary since the problems feared by Coneys are not realized in the inventive sheath. If a sandwiched structure of the type taught in Coneys is sliced into relatively short segments for use as a distal tip material, it would destroy the purpose of the tube, and furthermore, the embedded radiopaque layer would likely disengage from the surrounding virgin FEP of the tip at some point. In this event, the disengaged radiopaque FEP layer could cause harm to the patient by

becoming an embolus that is loose in the vasculature. This possibility is not present in the inventive device, where the radiopaque particles are dispersed throughout the matrix of the distal tip.

In addition, the sandwich structure of Coneys results in a radiopaque layer having an effective radiopaque loading of only 12-25%, which is much less than the radiopacity of the distal tip portion of the inventive sheath. As a result, the distinctiveness of the tip portion under fluoroscopy would be much less than that of the tip in the inventive sheath. When working with very small devices, such as stents, it is often important to know *exactly* where the stent is being placed. Indeed, if the device is misplaced the patient fails to achieve the full benefits of the device, and in some cases, can be harmed by the improper placement.

The present invention provides a very simple, cost effective FEP introducer sheath that has a highly loaded radiopaque FEP distal tip securely bonded to the main FEP shaft body. The cited combination of the Parker and the Coneys references fails to teach or even suggest such a sheath. As stated, Parker does not disclose or suggest the use of low friction FEP sheaths. A skilled artisan, with knowledge of both Parker and Coneys, would believe that it was not possible to obtain a highly loaded FEP tip, without utilizing the unnecessary and complicated sandwich structure taught by Coneys. Indeed, an artisan having knowledge of the Coneys patent might refrain from using FEP altogether, out of concern that the sheath would have insufficient radiopacity for use in remote vascular passages, and would not have a satisfactory coefficient of friction for use as an introducer sheath.

In order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. The suggestion to modify the art need not be expressly stated. Rather, it is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Citing references which merely indicate that isolated features recited in the claims are known is not a sufficient basis for concluding that the combination would be obvious, absent evidence of a motivating force which would impel persons skilled in the art to do what the applicant has done. Applicants respectfully submit that such motivation is lacking in the present application. Although the Coneys reference does speak of radiopacity and FEP, the teaching is so disparate from the

present invention that it would not have led the skilled artisan to combine its teachings with that of Parker to arrive at the present invention, absent the use of hindsight. In fact, perhaps a better case can be made that Coneys would have dissuaded the skilled artisan from using loaded FEP as a distal tip material.

Applicants respectfully submit that is improper to select an isolated passage from a reference to be used to support a particular premise, when the remainder of that reference actually shows that the premise is not a relevant or proper subject to be used against the present claims. Coneys suggests that that which Applicants have done cannot be done, or at the very least, should not be done. Since Applicants have proceeded in a direction contrary to the cited art, it is not proper to cite such references against the present claims under Section 103.

Thus, for the reasons provided above, Applicants submit that claim 1 and dependent claims 2, 4 and 13 are allowable over Parker in view of Coneys.

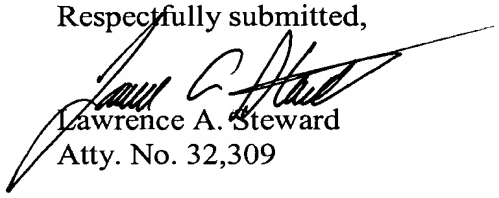
Claim 14 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Parker (270) in view of Coneys and Hopkins, and claims 5 and 6 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10, 13 and 16, and further in view of Hopkins. The Hopkins reference was cited for teaching the use of radiopaque materials such as tungsten in a catheter, and for teaching that particles can be as small as 0.9 microns, which, according to the Examiner, suggests that they can be any size larger than 0.9. The Hopkins patent is directed to a compliant marker band that is heat shrunk over a catheter or sheath, thus eliminating the need for heat or adhesive bonding. Col. 2, lines 34-36; Col. 3, lines 15-17. The marker band surrounds the external surface of the catheter or sheath and includes a radiopaque material such as tungsten.

By using a marker band, Hopkins teaches away from the present invention by employing technology that the present inventors desire to avoid. The use of a marker band that is heat shrunk or otherwise positioned over a sheath increases the thickness of the sheath wall, and thereby imparts a certain amount of rigidity to the sheath. In addition, the use of a radiopaque marker band forces the operator to estimate the precise location of the distal tip of the device. In the present invention, the radiopaque marker is the distal tip, thereby eliminating this guesswork. Applicants do not dispute that highly radiopaque marker bands are known in the art. However, the Hopkins reference does not teach or suggest the use of

FEP in an introducer sheath for the purposes described, nor does it teach or suggest that a distal tip can function as a radiopaque marker. In addition to the foregoing, one skilled in the art would not likely make the cited combination, since Hopkins also teaches away from a purpose of the present invention, namely the use of a highly loaded distal tip, instead of a marker band. Thus, Applicants respectfully submit that claims 5, 6 and 14 are allowable in view of the cited combination.

Based upon the remarks provided hereinabove, Applicants respectfully submit that all claims 1, 2, 4-6 and 13-14 are allowable over the combination of references discussed hereinabove. Accordingly, Applicants respectfully request that the Examiner reconsider the previous rejections in view of these claims. If the Examiner believes that prosecution of this application may be expedited by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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